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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,415	07/23/2003	Karl H. Weisgraber	UCAL-282	2272
24353	7590	01/25/2006	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			LEARY, LOUISE N	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/626,415

Applicant(s)

WEISGRABER ET AL.

Examiner

Louise N. Leary

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/8/07</u> | 6) <input type="checkbox"/> Other: ____ |

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1. Claims 1-20 are pending in this application.
2. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it is unclear if the "isolated apoE stable folding intermediate" is natural or man-made.

Claim 5 is indefinite because it is unclear whether a manual or automated technique is required for step "(b) determining the effect, if any, of said test agent on the lipid binding activity of apoE stable folding intermediate".

Claim 12 is indefinite because the metes and bounds intended for "in a solution" cannot be determined.

Correction is required to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Marrow et al

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(Biochemistry Vol. 39(38), pp. 11657-66, September 26, 2000, (ABSTRACT ONLY).

Marrow et al disclose a composition comprising an isolated apoE folding intermediate. Marrow et al address the stability of isolated apoE isoforms. Marrow et al disclose apoE folding intermediate was most prominent in apoE4. Marrow et al disclose apoE folding intermediate comprises a 22-kDa amino-terminal fragment. See the entire abstract.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-9,11-12, 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roses et al (US 6,027,896)(February 2000) in combination with Marrow et al (Biochemistry Vol. 39(38), pp. 11657-66, September 26, 2000, (ABSTRACT ONLY).

Roses et al disclose or suggest a method for determining the activity of apoE4 and characterizes an apoE4 related disorder. Roses et al disclose diagnosing Alzheimer's disease in a subject by detecting the presence of apoE4. Roses et al disclose " [The presence of ApoE4 indicates the subject is afflicted with Alzheimer's disease or at risk of developing Alzheimer's disease.]" Note the abstract. Roses et al also disclose "[A simple test is provided to determine whether an individual has the ApoE4 isoform, and whether the individual is homozygous for ApoE4 (i.e. produces only

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ApoE4) or is heterozygous for ApoE4 (i.e. produces ApoE4 and an additional isoform of ApoE.)” See column 2, lines 48-52. With respect to “an agent that reduces lipid binding”, Roses et al disclose binding of antibodies to apoE isoforms. Regarding a method for treating Alzheimer’s disease, Roses et al disclose using antibodies to selectively bind ApoE4. See column 7, lines 48-68 and column 8, lines 1-68. Further, Roses disclose chemicals that denature the apoE isoforms. See this entire document. Thus, Roses et al disclose the invention claimed except for using the phrase “an apoE stable folding intermediate.”

However, regarding “an apoE stable folding intermediate”, Marrow et al disclose an isolated apoE folding intermediate and address a direct nexus between an apoE folding intermediate and apoE4. Marrow et al address the stability of isolated apoE isoforms. Marrow et al disclose apoE folding intermediate was most prominent in apoE4. Marrow et al disclose apoE folding intermediate comprises a 22-kDa amino-terminal fragment. See the entire abstract.

Thus, Roses et al disclose the invention claimed except for addressing a nexus between an apoE folding intermediate and apoE4 which was provided by Marrow et al (Abstract Only) before this invention was made.

Therefore, it would have been obvious to one having ordinary skill in this art at the time this invention was made to provide a method of treating apoE-related disorder as claimed because, Roses et al disclose the invention claimed except for addressing a nexus between an apoE folding intermediate and apoE4 that was provided by Marrow et al (Abstract Only) which renders the invention as claimed obvious.

(II) Claims 16-17, and 19- 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poirier (US 6,022,683)(February 2000) in combination with Marrow et al (Biochemistry Vol. 39(38), pp. 11657-66, September 26, 2000, (ABSTRACT ONLY).

Poirier disclose or suggest treating apoE-related disorder by administering a pharmaceutical. Poirier disclose treating neurological diseases in clinical trails. Also, Poirier disclose "[Apolipoprotein E (apoE) functions as a ligand in the process of receptor mediated internalization of lipid-rich lipoproteins....]" See column 1, lines 1-68 and column 2, lines 1-68. With respect to the limitations of claims 17 and 19, Poirier disclose treating non-Alzheimer's diseases associated with apoE isoforms. See this entire document. In regards to the limitations of instant claim 20, Poirier disclose treating stroke which is known to be a "cardiovascular disease" in this art. Thus, Poirier disclose the invention claimed except for addressing "an apoE folding intermediate".

However, regarding addressing "an apoE folding intermediate", Marrow et al (Abstract Only) disclose a nexus between an apoE folding intermediate and apoE isoforms.

Hence, Poirier disclose the invention as claimed except for addressing "apoE-folding intermediate" which was provided by Marrow et al (Abstract Only) before this invention was made.

Therefore, it would have been obvious to one having ordinary skill in this art at the time this invention was made to provide a method of treating apoE-related disorder

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as claimed because , Poirier discloses the invention claimed except for addressing a nexus between an apoE folding intermediate and apoE isoform that was provided by Marrow et al (Abstract Only) which renders the invention as claimed obvious.

5. Claims 10, and 13-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims..

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is 571-272-0966. The examiner can normally be reached on Monday to Friday from 10 to 6:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey, can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LOUISE N. LEARY
PRIMARY EXAMINER

January 23, 2006